Staged Protocol for the Treatment of Chronic Tibial Shaft Osteomyelitis With Ilizarov’s Technique Followed by the Application of Intramedullary Locked Nail

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Abstract

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Open tibial shaft fractures are the most common open fractures, and many complications can occur. During the treatment period, infection leading to osteomyelitis was the most common complication. However, no consensus exists regarding the ideal management for such cases in the literature.

The purposes of this retrospective study were to review the treatment of patients with chronic tibial shaft osteomyelitis over the past 14 years who were referred to the authors’ institution and to provide a staged protocol for spontaneous wound healing. The staged protocol included: (1) radical debridement for infected bone and soft tissue; (2) immediate application of Ilizarov’s apparatus for all patients except those needing delayed application; (3) osteotomy in healthy bone; (4) simultaneous distraction–compression osteogenesis and histogenesis; (5) additional docking-site bone grafting; and (6) shifting the external fixator to a locked nail when callus formation was visible at the distraction site. Union was achieved in 15 of 16 patients, with an average external fixation time of 4.5 months (range, 3–6 months). No deformity or leg-length discrepancy greater than 1 cm occurred.

In the treatment of chronic osteomyelitis, this staged protocol was safe and successful and allowed for union, realignment, reorientation, and leg-length restoration. Regarding the soft tissues, this technique provides a unique type of reconstructive closure for infected wounds. It is suggested that the staged protocol is reliable in providing successful simultaneous reconstruction for bone and soft tissue defects without flap coverage.

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Tibial diaphyseal fractures are the most common open fractures. More than 50% of open fractures in the authors’ institution are classified as high-energy Gustilo-Anderson type III fractures. Many complications can occur, including nonunion, malunion, delayed union, bone and joint deformities, chronic edema, compartment syndrome, limb-length discrepancy, infection, and amputation.1-5

In the experience of the surgeons of the Taipei Veterans General Hospital, it is difficult to treat the comminuted fractures in Gustilo-Anderson type III fractures with only standard intramedullary nailing or internal fixation, particularly in the setting of large bone and soft tissue defects. Although autogenous bone grafting may be used to fill bone defects, donor-site morbidity and insufficiency exist in large segmental defects, in which case the autogenous bone grafting could be performed only as a secondary procedure. Furthermore, the management of these fractures is complicated by concomitant neurovascular and soft tissue injuries, which cause the risks of limb infection and amputation. In the event of complete bony union, these treatment difficulties may lead to the functional decline of limbs with limb-length discrepancy, deformities, and joint contracture.

Soft tissue damage around the fractures and subsequent wound management are often the main factors affecting the outcomes of open tibial fractures. During tibial bone fixation, early application of either a local muscle flap or a free flap may be the appropriate treatment, respectively, for the defect around the proximal two-thirds or the distal one-third of the tibia. However, the local flap can be suboptimal because the rotated muscle often falls in the severe injury zone. However, the application of a free flap requires microsurgery and local blood supply, which may have been compromised by vascular injuries.

Over the past 3 decades, external fixation has become a prominent method for achieving union in comminuted fractures, correcting angular deformity, and reconstructing bony defects using distraction osteogenesis.6-8 This surgery is performed percutaneously to minimize soft tissue trauma. Advanced techniques using the Ilizarov method can provide healing capacity for large bone and soft tissue defects without the need for flap coverage and provide an alternative to amputation.9 Distraction histogenesis has also been used for skin expansion around the contracture joint.10

In the current study, infection leading to osteomyelitis was considered the most common complication. However, no consensus exists regarding the ideal management of osteomyelitis after treating open tibial shaft fractures in the literature. The purposes of the current retrospective study were to review the treatment of patients with chronic tibial shaft osteomyelitis over the past 14 years who were referred to the authors’ institution (Taipei Veterans General Hospital) and to provide a staged protocol for spontaneous wound healing using wet-to-dry dressing followed by simultaneous distraction–compression osteogenesis or histogenesis of Ilizarov’s technique to restore the soft tissue defects and the bony gap without further flap coverage and autogenous cancellous bone grafting for the docking site. The external fixator was shifted early to an intramedullary locked nail when callus formation was visible at the distraction site.

Materials and Methods

Demographic Data

Between October 1997 and March 2012, sixteen patients with chronic osteomyelitis and soft tissue loss around the tibial shaft underwent this protocol at the authors’ institution. Prior to staged manage-
The patient sustained an open segmental tibial shaft fracture with infection and had been treated with intramedullary locked nail at another institution approximately 3 months before presentation. The staged protocol of the clinic was applied. Anteroposterior (A) and lateral (B) radiographs and photograph (C) showing the condition on arriving. Anteroposterior radiograph showing postoperative status after radical debridement, removal of locked nails, sequestrectomy, and residual 12 cm of bone defect (D). Anteroposterior (E) and lateral (F) radiographs showing that bone transport was performed with a trifocal-approach. Anteroposterior (left) and lateral (right) radiographs showing visible callus (G). Photograph taken on arrival at the docking site showing Ilizarov’s apparatus with an extended fixator for forefoot anchorage (H). Anteroposterior (I) and lateral (J) radiographs obtained after removing the external skeletal fixator showing intramedullary locked nail and bone consolidation after Harmon’s procedure. Anteroposterior (K) and lateral (L) radiographs showing bony union at 1-year follow-up.

**Figure 2:** The patient sustained an open segmental tibial shaft fracture with infection and had been treated with intramedullary locked nail at another institution approximately 3 months before presentation. The staged protocol of the clinic was applied. Anteroposterior (A) and lateral (B) radiographs and photograph (C) showing the condition on arriving. Anteroposterior radiograph showing postoperative status after radical debridement, removal of locked nails, sequestrectomy, and residual 12 cm of bone defect (D). Anteroposterior (E) and lateral (F) radiographs showing that bone transport was performed with a trifocal-approach. Anteroposterior (left) and lateral (right) radiographs showing visible callus (G). Photograph taken on arrival at the docking site showing Ilizarov’s apparatus with an extended fixator for forefoot anchorage (H). Anteroposterior (I) and lateral (J) radiographs obtained after removing the external skeletal fixator showing intramedullary locked nail and bone consolidation after Harmon’s procedure. Anteroposterior (K) and lateral (L) radiographs showing bony union at 1-year follow-up.

ment, each patient had a complete examination, including electromyography, angiography, and triple-film radiographs of the lower limbs. Inclusion criteria were: an absence of pin-tract infection when shifting the external fixator to a locked nail and a suitable space in the intramedullary canal to accommodate a locked nail. Fourteen men with a mean age of 36 years (range, 18-70 years) were selected. Ilizarov’s apparatus (Smith & Nephew Richards, Memphis, Tennessee) was used after the removal of previous implants, the performance radical debridement, or both. Full weight bearing was allowed to enhance callus maturation during the distraction stage. The average length of the bone and soft tissue defects after radical debridement was 8 cm (range, 4-12 cm). The latency period was 7 days, followed by simultaneous distraction–compression osteogenesis and histogenesis after osteotomy in healthy bone. A bone defect longer than 6 cm was an indicator of trifocal transport. Temporary extended fixator for anchorage of the forefoot was used in each case to avoid the relative complication of equinus deformity. Additional bone grafting was performed around the docking site in all patients.

**Strategies**

The staged protocol (Figures 1A-H, 2A-L) for treating chronic osteomyelitis and soft tissue loss around the tibial shaft included: (1) radical debridement for infected bone and soft tissue and the additional insertion of an antibiotic-impregnated cement-rod for 10 days in cases of previously existing septic medullary implant; (2) the immediate application of Ilizarov’s apparatus for all patients except those needing delayed application because of previously existing septic medullary implant; (3) osteotomy in healthy bone; (4) simultaneous distraction–compression osteogenesis and histogenesis; (5) additional docking-site bone grafting; and (6) shifting the external fixator to a locked nail with a closed technique when callus formation was visible at the distraction site. Vancomycin was used throughout treatment for all patients.

**Radical Debridement.** Performing radical debridement before the Ilizarov’s procedure is necessary. With regard to infected bone, adequate debridement should supply a healthy appearance of the remaining bone with an opened intramedullary canal and bleeding surface, which is best performed under the use of tourniquet. During sequestrectomy, the typical bone cut is made perpendicular to the anatomic tibial axis using a power saw cooled with saline irrigation. Under C-arm fluoroscopy, a K-wire is used as a guide for the bone cut. The remaining bone edges require soft tissue coverage to avoid desiccation, secondary necrosis, and osteomyelitis. When determining the amount of diseased bone removed, the bone quality priority, rather than bone volume, was adopted. The remaining bone surfaces had visible bleeding spots and serosanguinous fluid discharged from the opened intramedullary canal or the multiple pin tracts made on the cancellous bone. The surgical wound was left open, and wet dressing was necessary. Then, the presence of granulation tissue around the proximal or distal bone surface ensured the previously adequate debridement. However, the soft tissue defect was ideally fashioned into a basin-like shape, which provided histo-
genesis a platform to approximate wound edges. The Ilizarov’s apparatus was applied immediately following radical debridement.

Ilizarov’s Apparatus. To set up the Ilizarov’s apparatus, the surgeons placed two 4-mm full pins with central threads (Smith & Nephew Richards), which were parallel to the joint line under the guidance of fluoroscopy, through the proximal and distal tibia for stronger connections with up- and nethermost rings, respectively. All rings of the Ilizarov’s apparatus should be arranged concentrically. Most of the connections were 1.8-mm smooth or olive wires through the tibia, perpendicular to the tibial axis, and with 2 ends fixed on the ring. For each ring block, 1 wire was applied as a reference on the coronal tibial plane. Then, another wire was accordingly applied next to the first wire, forming a transverse ring plane. The clearance between the soft tissue and the rings was approximately 2 fingerbreadths. A tension of 110 kg was suggested for fixing smooth wires, whereas 90 kg was suggested for olive wires. An additional 5-mm half-pin was selectively applied in the adaptive site to enable the ring more stability on the plane perpendicular to the tibial axis. Therefore, setting each ring block should have a combination of 2 wires with or without 1 half-pin. All wires and pins were placed through the safe zone to avoid neurovascular structure injury.

Osteotomy. The subsequent osteotomy in healthy bone was suggested 1 week after applying the external fixator. When a short bone segment is left after an osteotomy in the proximal or distal tibia, extending the circle frame across the knee or ankle joint should be considered, at least temporarily. In the experience of the surgeons of the Taipei Veterans General Hospital, the strategy is most commonly used for the distal tibia. Using the intraoperative olive-wire reduction technique, the bone defect edges should be perfectly pointed toward each other to avoid deviation during bone transport and to optimize contact at the anticipated docking site.

Simultaneous Distraction–compression Osteogenesis and Histogenesis. With the adjustable rods longitudinally applied between the rings, simultaneous distraction–compression osteogenesis and histogenesis were administrated 7 days after osteotomy. Osteogenesis was periodically monitored during the first postoperative month and after full weight bearing. During the Ilizarov procedure, monofocal, bifocal, and trifocal approaches were the 3 novel approaches chosen for bone and soft tissue transport. In the monofocal approach, the 2 bony segments next to the defect were transported toward each other, which caused limb shortening. An osteotomy was performed outside of the healthy bone injury zone using a bifocal approach (Figure 1B). The intercalary segment was then transported and compressed the defect site (Figures 1C-E). A simultaneous lengthening occurred through the corticotomy site, which maintained the limb length. A trifocal approach (tandem procedure), which was indicated when a bone loss of more than 6 cm occurred (Figure 2D), used 2 lengthening osteotomies and compression of the defect (Figure 2E). The Ilizarov method of intercalary bone transport was used to treat tibial bone loss and achieve limb salvage.

Bone Grafting. After the periodic assessment of regenerated bones, bone marrow injection was indicated in patients with slow maturation of regenerative bone at the 2-month follow-up. Additional bone grafting also improved docking site healing after wound closure and eradicated infection in all patients. Using Harmon’s procedure with posterolateral grafting at the middle and distal tibia was recommended.

Intramembranous Locking Nail Application. When callus formation was visible at the distraction site, it was considered the appropriate time to apply the intramembranous locking nail (Smith & Nephew Richards). However, when callus formation was visible at the distraction site, regenerative solid bone existed on the pathway leading to higher technique demand for intramedullary nailing. Under an external fixator for keeping the anatomical reduction, a long, rigid guide-pin (Rush Pin LLC, Meridian, Mississippi) with sharp ends was used to make a tract break through the regenerative callus. Then, the locking nail (Smith & Nephew Richards) was introduced across the docking site after adequate reaming. A locked intramedullary nail was applied after adequate reaming.

Wound Management Principles

Necrotic and devitalized tissues should be debrided while preventing exposure of the remaining healthy bone. The wounds should be left accessible, with the leg in the circle frame. Several self-incremental adjustments were made on each day. Patient involvement and cooperation were important while using this method. The self-care of wounds was also essential during the transporting phase until closure occurred. In most patients, the wounds were managed with daily normal saline wet-to-dry dressing during the transporting phase until closure occurred. In addition to normal saline, diluted H2O2 (about 1:1) in wet gauze as a disinfectant for treating wounds 3 days postoperatively (radical debridement) was used and kept for 2 more weeks. More recently, a vacuum-assisted closure (VAC) device was used on open wounds during the transporting phase. As the transport progressed, the granulation tissue was expected to appear, and the wound size gradually decreased until the wound healed.

RESULTS

Union was achieved in 15 of 16 patients, with an average time to external fixation of 4.5 months (range, 3-6 months). No deformity or leg-length discrepancy greater than 1 cm occurred. Bone marrow injection to the regenerate site was 15%. One patient had a recurring infection but refused further treatment.
**DISCUSSION**

An innovative alternative to compensate for bone loss is to transport healthy bone to the fracture site to bridge the bone defect. The dynamic frame enables gradual lengthening, deformity correction, and compression of nonunion or delayed union with minimal invasion. The soft tissue envelope regenerates around the bone transport. The bone transport technique was initially reported as distraction osteogenesis by Ilizarov, and then became widely used by orthopedic surgeons in the West. However, this method also has disadvantages, including a prolonged external fixation period.

Regarding soft tissue loss, the early application of muscle-flap coverage was often considered a procedure that provided an infection barrier and promoted healing. Many have also reported that using appropriate soft tissue coverage is necessary for preventing infection and bone desiccation. Regardless, some problems remain in the extensive soft tissue injuries and vascular disruption in severe tibial fractures. Thus, opinions for flap coverage may be limited. On occasion, plastic surgeons state that patients are not candidates for flap reconstruction due to local soft tissue unavailability, potentially poor vascular supply (eg, single vessel, preexistent procedure of revascularization, or plaque disease of vessels), and systemic comorbidities that make patients intolerant to time-consuming surgery. In addition, another flap coverage revision is almost infeasible after previous flap necrosis. With a lack of adequate wound coverage, many patients may face inevitable osteomyelitis and amputation.

Overall, many methods exist for the obliteration of the dead space after radical debridement for necrotic bone and soft tissue, including exteriorization, plombage, cancellous bone grafting or bone substitutes, transfer of living tissue, and the simultaneous treatment of bone and soft tissue with Ilizarov’s method. The Ilizarov method, which can be used successfully to reconstruct legs with tibial bone loss and soft tissue defects simultaneously, was chosen for the current patients. This limb-salvage method can be used in patients who are not candidates for flap coverage. Another concern regarding the use of this technique was to prevent patients from possible failure of flap coverage. Gradual defect closure was accomplished, resulting in bone and soft tissue healing. Limb lengthening can be performed outside the injury zone in healthy bone and soft tissue. A trifocal approach should be considered for defects larger than 6 cm. Technique and frame design advances should help prevent residual deformity.

The priority of reconstructive methods for soft tissue defects is controversial and may create a dilemma for surgeons in determining whether soft tissue transport should be used as the last resort only when flap coverage is not available or if it should be used as the priority to avoid possible flap coverage failure. Previous reports showed that simultaneous bone and soft tissue transport could successfully avoid the need for flap coverage. The final choice depends on the surgeon’s preference and the availability of plastic surgeons. The treatment time is long, and patients report pain, especially during the transporting phase. Potential complications include limb-length discrepancy, malalignment and malorientation, joint contracture, pin-track problems, nonunion, refracture, recurrent infection, and limb loss.

Although potential complications existed in previous studies, no irreversible complication occurred from the procedure during distraction–compression osteogenesis and histogenesis in the current study. Minor complications were resolved with conservative treatments, whereas major complications required additional surgery. Mild pin-track infections were treated by local care and oral antibiotics. For severe pin-track infections, surgical debridement was performed with exchanging wire/screw and intravenous antibiotic therapy. Distraction-area pain was the most common report during the transporting phase. In the patients who needed lengthening of more than 4 cm, dermal irritation from wires and screws that increased pain happened more frequently. Otherwise, the increased pain would be relieved by oral analgesics.

Staged management for chronic tibial shaft osteomyelitis is a top standard. Staged management for infected tibial shaft nonunion followed by locked intramedullary nailing had been reported by Klemm via 3 or 4 stages. In this research, the principles of staged management were followed, and the intramedullary locked nail provided stable fixation via a closed technique. Insertion of the interlocking nail at the same time as the external fixation was supposed to be avoided in previous studies because of concerns of potential infection. However, early removal of the external fixator and replacement by intramedullary nail achieved the same clinical and functional outcome as the classic technique with a shorter duration of external fixation. Furthermore, the suggested adequate time to perform nailing was when callus formation was radiographically visible at the distraction site because the intramedullary implant could occupy the healing space for osteogenesis.

**CONCLUSION**

In the treatment of chronic osteomyelitis, the staged protocol proposed by the authors is safe and successful. The same techniques that were used for all cases allow for union, realignment, reorientation, and leg-length restoration. Regarding the soft tissues, this protocol provides a unique type of reconstructive closure for infected wounds. The cases of tibial open fractures with complicated osteomyelitis and soft tissue loss in the past 14 years were retrospectively reviewed, and it is suggested that the staged protocol is reliable in providing successful reconstruction simultaneously for bone and soft tissue defects without flap coverage.
REFERENCES


